UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HUMANA INC., Plaintiff, v. CELGENE CORPORATION, Defendant.	Case No. 2:19-CV-07532-ES-MAH HON. ESTHER SALAS HON. MICHAEL A. HAMMER

MEMORANDUM OF LAW IN SUPPORT OF CELGENE CORPORATION'S MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

STATE CASES

INTRODUCTION

Humana Inc., one of the country's largest insurers, brings this suit against Celgene for alleged damages on purchases and/or reimbursements of Celgene's oncology products Thalomid® and Revlimid®. Humana sat back and watched the same issues be litigated over the last decade, and now purports to recycle those allegations in a complaint of its own. Humana's suit is neither original nor timely.

This Court is quite familiar with Humana's core allegations—that Celgene allegedly refused to sell product samples to competitors so as to keep them out of the marketplace—given that Mylan alleged the very same conduct in a suit filed in this Court in April 2014. Humana copies the allegations of Mylan and others, allegations purporting to reach conduct as far back as 2004. Humana's claims would have been untimely even had they been filed at the same time as Mylan's Complaint due to public notice of, among other things, a June 2009 petition to the FDA by another generic company regarding the issue of Thalomid and Revlimid samples, and then the February 2010 disclosure of an FTC investigation into these same matters.

Humana, however, waited several more years—indeed, even several more years after Mylan sued in 2014—to bring this case. If Humana, a sophisticated player in the pharmaceutical industry, truly anticipated generic competition to begin on Thalomid in ***2006*** and Revlimid in ***2009***—as its Complaint now claims—it could have and should have filed this lawsuit a decade ago.

In an attempt to cure the obvious statute of limitations problem with its case, Humana pivots from the stale samples issue to lob allegations about patent infringement suits that Celgene has filed more recently—claiming that virtually every

such suit Celgene has ever filed on Thalomid or Revlimid was a "sham." In the Third Circuit, pleading such a claim is "an uphill battle," requiring Humana to show that the litigation was so "objectively baseless" that no litigant could have expected a favorable outcome. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class,* 868 F.3d 132, 147-48 (3d Cir. 2017) (internal quotation marks omitted).

Humana comes nowhere close to sufficiently pleading such allegations. And for good reason. Generics' patent challenges to Celgene's patents have been unsuccessful: Barr Laboratories, the first company to file an Abbreviated New Drug Application (ANDA) on Thalomid, abandoned its challenge in 2010 after multiple years of patent litigation; Lannett, the second such filer, settled its 2015 Thalomid patent litigation with Celgene and agreed to a patent license not beginning until August 2019; Natco Pharma, the first generic to file an ANDA on Revlimid, settled for a license beginning in March 2022; and, more recently, the Patent Office (PTO) has rejected a series of petitions filed by other generics seeking to challenge Celgene's Revlimid patents via *inter partes* review (IPR). Indeed, when Mylan sued Celgene, Mylan conceded that even had it bought samples of Revlimid in 2008, it would not have begun selling generic Revlimid any sooner than 2022, in view of Celgene's patents. Humana cannot claim a right to have been able to buy a generic product from generic companies earlier than those companies themselves claim they would have been able to lawfully sell one.

For these reasons, Humana's Complaint should be dismissed now for failure to state a claim. *Infra*, Part I. Yet, even were Humana's theories of liability viable, the Court can and should dismiss now two subsets of its claims. *First*, Humana purports

to plead claims on behalf of unnamed entities on whose behalf it seeks to "pursue recovery"; but Humana does not name those entities, and cannot establish standing to proceed on their behalf. *Infra*, Part II. *Second*, Humana's state law claims, brought as a so-called "indirect purchaser" of these drugs, fail for several reasons: (i) they are time-barred; (ii) Humana merely lists claims, failing to actually plead them; and (iii) the claims fail to comply with state-specific requirements. *Infra*, Parts III & IV.

Celgene respectfully submits that Humana's Complaint should be dismissed.

BACKGROUND

The products at issue revolve around the drug thalidomide, the infamous history of which the Court is well aware from overseeing the *Mylan* litigation. After years of research, and conditioned on severe distribution restrictions, Celgene obtained FDA approval of thalidomide in 1998, which it markets as Thalomid. Compl. ¶ 2. And in 2005, Celgene successfully developed a new product, lenalidomide, marketed as Revlimid. *Id.* ¶ 3. These drugs have been immensely popular due to their ability to prolong the lives of thousands of patients afflicted with blood borne cancers, such as multiple myeloma. *Id.* ¶¶ 8, 89, 92.

Given the history of thousands of deaths and birth defects when thalidomide was sold by other companies abroad, the FDA conditioned its approval for Celgene to sell Thalomid on implementation of a restricted distribution program, the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S."). *Id.* ¶ 88-89. Because Revlimid may pose the same fetal exposure concerns, its approval was also subject to a distribution program called RevAssist. *Id.* ¶ 93. These are FDA-approved Risk Evaluation and Mitigation Strategies ("REMS") programs, designed to

"mitigate fetal exposure" to Thalomid and Revlimid. *Id.* ¶¶ 89-93.

***Intellectual Property*:** Celgene was awarded various patents to protect its innovations. Given that thalidomide is not itself a Celgene invention, Celgene did not patent the compound; but it does hold patents claiming, among other things, the method of using thalidomide, in combination with dexamethasone, to treat blood-borne cancers, as well its particular drug product formulation. The last of these patents expires in 2023. *Id.* ¶ 96.

Celgene also was awarded several patents on Revlimid. *Id.* ¶ 96. The patent on the active pharmaceutical ingredient in Revlimid, lenalidomide, which Celgene scientists invented, does not expire until October 2019, and the additional patents covering methods of using the product do not expire until 2028. *Id.* ¶¶ 96, 242. Celgene also was awarded various regulatory exclusivities, such as Orphan Drug Exclusivity intended to reward research into diseases that afflict smaller populations, and a New Chemical Exclusivity on Revlimid lasting five years, because lenalidomide was a "new chemical entity." *Id.* ¶¶ 3 n.2, 92.

Celgene's Revlimid patents in particular are widely recognized to be impregnable; just in the last few months, the Patent Trial and Appeal Board ("PTAB") has rejected five IPR challenges to Revlimid patents, including for a patent that does not expire until 2028.[1] Prior to that, in 2015, the PTAB also refused to institute an IPR challenge to the validity of Celgene's patent on the lenalidomide

[1] *See* Decision Denying Institution of *Inter Partes* Review, *Apotex Inc. v. Celgene Crop.*, No. IPR2018-00685 (P.T.A.B. Sept. 27, 2018), https://www.1600ptab.com/wp-content/uploads/sites/27/2018/10/Apotex-Inc.-v.-Celgene-Corp.-IPR2018-00685-DDI.pdf.

compound,[2] which as noted does not expire until October 2019, and so would have lawfully blocked any generic competition to Revlimid to this point.

***Prior Litigation*:** Humana's claims are a copy of other lawsuits going back over the last decade. Humana's Complaint copies, nearly *verbatim*, allegations made by Barr in a public pleading dating back to 2007. *See Celgene Corp. v. Barr Labs., Inc.*, No. 07-cv-00286, Dkt. No. 9 (D.N.J. March 1, 2007) ("Barr Compl."). Humana also cites the allegations of Lannett, another generic, which sued Celgene for antitrust violations regarding product samples, litigating the issue from 2008 through 2011. *Lannett Co. v. Celgene Corp.*, No. 08-3920, Dkt. No. 1 (E.D. Pa. Aug. 15, 2008) ("Lannett Compl."). Finally, Humana relies on the claims Mylan filed in 2014. *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094 (D.N.J. Apr. 3, 2014) ("Mylan Compl.").

There was, indeed, even more public information at Humana's disposal. In 2009, Dr. Reddy's Laboratories ("DRL"), filed a Citizen Petition with the FDA alleging that Celgene was delaying generic competition by withholding samples of Thalomid and Revlimid.[3] And in 2010, Celgene publicly disclosed an FTC investigation regarding "requests by generic companies to purchase [Celgene's] patented THALOMID® and REVLIMID® brand drugs" and whether there was reason to believe Celgene had "engaged in unfair methods of competition." Ex. 3,

---

[2] Ex. 1, Decision Denying Institution of *Inter Partes* Review, *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, No. IPR2015-01169 (P.T.A.B. Nov. 16, 2015).

[3] *See* Ex. 2, Citizen Petition from DRL, No. FDA-2009-P-0266 (posted June 15, 2009), https://www.regulations.gov/document?D=FDA-2009-P-0266-0001. The FDA subsequently denied the petition to the extent it sought any action against Celgene. FDA Response to DRL Citizen Petition, No. FDA-2009-P-0266 (posted Aug. 9, 2013), https://www.regulations.gov/document?D=FDA-2009-P-0266-0006.

Celgene Corp., Annual Report (Form 10-K) (Feb. 18, 2010); *see also* Ex. 4, Celgene Corp., Annual Report (Form 10-K) (Mar. 1, 2011). The FTC later closed the investigation without any action against Celgene.[4]

Humana's Allegations*:** To distract from the facial untimeliness of its Complaint, Humana alleges a sprawling case, but which in essence boils down to: (1) Celgene prevented competitors from obtaining samples of Thalomid and Revlimid, in order to prevent them from conducting bioequivalence testing; and (2) ***all of Celgene's patent infringement claims against potential generic competitors have been "sham litigation," because of the assertion of certain patents that, according to Humana, were procured through fraud on the PTO.

For the majority of its allegations, Humana reaches back to conduct that is far outside of the statutes of limitations, and on that basis alone, Humana's claims should be dismissed as untimely. Humana has attempted to "refresh" its claims by asserting that all of Celgene's patent infringement suits, including suits filed in the last couple of years, were based on "fraudulent" patents. The law discourages plaintiffs from throwing around claims of "fraud," whether on the PTO or anyone else; and such claims are required to be pled in this context to an extraordinary standard of particularity. Humana comes nowhere close.

Humana no doubt hopes that filing a 100+ page complaint, and mixing and matching allegations from several different dockets, would skate its pleading by 12(b)(6) review. But breadth is no substitute for substance, and it certainly is no basis

[4] *See* Ltr. from Donald S. Clark to Phillip A. Proger (Oct. 31, 2017), https://www.ftc.gov/system/files/documents/closing_letters/nid/0810172_celgene_corporation_closing_letter_to_counsel_for_celgene.pdf.

to resurrect untimely claims. Its Complaint should be dismissed.

LEGAL STANDARDS

To survive a motion to dismiss, a complaint must allege a basis for liability that is plausible and supported by non-conclusory allegations. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). "Mere 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Havens v. Mobex Network Servs., LLC*, No. 11-993 (KSH), 2011 WL 6826104, at *3 (D.N.J. Dec. 22, 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Moreover, a court need not accept as true conclusory statements or "legal conclusions masquerading as facts." *U.S. Claims, Inc. v. Flomenhaft & Cannata, LLC*, 519 F. Supp. 2d 515, 520 (E.D. Pa. 2006).

Humana must plead claims of fraud on the PTO "with particularity [as to] the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also Exergen Corp. v. Wal–Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). The patent challenger must establish, ***by clear and convincing evidence***, "that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO." *Id.* at 1287. The particularity standard of Rule 9(b) "requires identifying the specifics of who, what, when, where, why, and how of the material misrepresentation/omission before the PTO." *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, 325 F.R.D. 90, 94 (D.N.J. 2018) (citing *Exergen*, 575 F.3d at 1328).

The defense of inequitable conduct may also be the basis of a so-called "*Walker Process*" antitrust claim, where a challenger alleges a patent holder fraudulently acquired a patent. *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1341 (Fed. Cir. 2007). *Walker Process* claims are also subject to Rule 9(b), and require alleging:

> 1. A false representation or deliberate omission of a fact material to patentability[,] 2. made with the intent to deceive the patent examiner[,] 3. on which the examiner justifiably relied in granting the patent, and 4. *but for* which misrepresentation or deliberate omission the patent would not have been granted.

In re Remeron Antitrust Litig., 335 F. Supp. 2d 522, 528 (D.N.J. 2004) (quoting *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998)). *Walker Process* claims are at least as difficult to plead as inequitable conduct; "*Walker Process* fraud and inequitable conduct are fraternal twins," but "*Walker Process* fraud is a more serious offense than inequitable conduct." *Xitronix Corp. v. KLA-Tencor Corp.*, 757 F. App'x 1008, 1010 (Fed. Cir. 2019) (per curiam) (quoting *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998)); *accord In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389 PGS, 2013 WL 4780496, at *19 (D.N.J. Sept. 5, 2013) (*Walker Process* claim must meet a "higher standard" than inequitable conduct).

Generally, a patent holder seeking to enforce a patent has a First Amendment right to petition the government and have access to the courts. *See Wellbutrin*, 868 F.3d at 147 (citing *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993)). That protection is the basis of the "*Noerr-Pennington* doctrine," which immunizes such a patent holder from antitrust liability when it brings a lawsuit. *Id.* Sham litigation is a narrow exception to *Noerr-Pennington* immunity and the claim

requires pleading, among other things, that the lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* at 148 (quoting *Prof'l Real Estate Inv'rs, Inc.*, 508 U.S. at 60). A party alleging sham litigation "faces an uphill battle," *id.* at 147, given that it is an exception to the First Amendment. This already high burden is "higher still" in the context of a patent suit against an ANDA filer, because the act of filing an ANDA is itself an act of infringement per the express provisions of the Hatch-Waxman Act. *Id.* at 149.

Finally, in ruling on a motion to dismiss, a court may consider the complaint's allegations, exhibits attached to the complaint, matters of public record, and other documents integral to or explicitly relied on in the complaint. *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014); *see also S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp.*, 181 F.3d 410, 426 (3d Cir. 1999) (district court may take judicial notice of public records, including judicial proceedings, to resolve a motion to dismiss).

ARGUMENT

I. Humana's Antitrust Claims Should be Dismissed.

Humana's Complaint focuses overwhelmingly on conduct that allegedly occurred a decade or more ago, about which generic manufacturers began making claims as early as 2008 and 2009 (Lannett and DRL), which was investigated by the FTC (as publicized in 2010), and which was litigated in this Court beginning in 2014 (by Mylan). Humana cannot state a claim based on such conduct in 2019. In particular, the allegation that Humana currently pays "supracompetitive prices," Compl. ¶ 11, as a result of decade-old conduct is insufficient as a matter of law, as the statute of limitations prohibits recovery based on current alleged effects of conduct

outside the limitations period. And the few scattered allegations of recent conduct are not sufficiently pled to serve as the basis for a stand-alone antitrust claim.

A. Humana's Antitrust Claims Are Untimely.

Humana's federal claims are subject to a four-year statute of limitations, 15 U.S.C. § 15b, and with few exceptions its state law claims are subject to statutes of limitations of four or fewer years.[5]

In antitrust cases, "generally 'a cause of action accrues and the statute [of limitations] begins to run when a defendant commits an act that injures a plaintiff's business.'" *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 106 (3d Cir. 2010) (alteration in original) (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971)). Thus, the four-year statute of limitations begins to run on an antitrust claim at "the point the act first cause[d] injury" to the plaintiff. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 190-91 (1997).

The core of Humana's case turns on alleged conduct that occurred well outside the limitations period and therefore provides no basis for relief. Specifically, Humana asserts claims based on the following, all of which occurred before June 2014 (*i.e.*,

[5] Aside from Mississippi, which has a three-year statute of limitations for antitrust claims, most of the remaining states under which Humana asserts antitrust violations impose a four-year limitations period: Arizona, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Utah, and West Virginia. Humana's antitrust claims under Maine, Vermont, and Wisconsin law are subject to six-year limitations periods. *See* Appendix A. For the statutes of limitations for Humana's other state-law claims, *see infra* Part IV.A and Appendix A.

more than four years before the effective filing date of the Complaint):[6]

- Alleged refusal to sell Thalomid samples to various companies between 2004 and 2008, see e.g., Compl. ¶¶ 110-33, 168-187, 213-218, 379;
- Alleged refusal to sell Revlimid samples to various companies between 2008 and 2013, see e.g., Compl. ¶¶ 135-156, 196-218;
- The settlement of Lannett's antitrust lawsuit regarding Thalomid samples, filed in 2008 and settled in 2011, which settlement Humana says only "may" have been anticompetitive, Compl. ¶¶ 5, 188-195;
- Alleged delay of Barr's ANDA by means of an exclusive supply agreement dating to 2005, a 2007 Citizen Petition, and a 2010 purported settlement with Barr that "may" have been anticompetitive, Compl. ¶¶ 5, 219-231, 325-338; and
- Alleged sham patent infringement litigation filed against Natco regarding its Revlimid ANDA in 2010 and settled in 2015, Compl. ¶¶ 345-358.

On the back of these allegations, Humana claims that generic versions of Thalomid and Revlimid should have been available for its purchase in 2006 and 2009, respectively. Compl. ¶¶ 379-380. Humana thus alleges that these acts first caused it injury far outside the statute of limitations. Accordingly, the statute of limitations on those allegations began to run (at the latest) on the date the alleged injurious conduct occurred, *see W. Penn Allegheny Health Sys.*, 627 F.3d at 106; *Klehr*, 521 U.S. at 190-91, and expired four years later, well before the effective filing date of the Complaint. Humana's claims should therefore be dismissed.

Notably, Humana has not alleged—nor could it—that the statute of limitations should be tolled by any concealment or ignorance of its claims. For one thing, such allegations would be irrelevant; the law is clear that mere ignorance of an antitrust

[6] Humana negotiated a tolling agreement that covered a limited period—from September 2017 through May 2018. This results in Humana's Complaint being treated as filed nine months earlier, *i.e.*, in June 2018, instead of March 2019.

claim does not toll the statute of limitations. *See Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 246 & n.8 (3d Cir. 2001) ("antitrust claims are subject to the less plaintiff-friendly 'injury occurrence' accrual rule" rather than a "'discovery' rule"). But apart from the legal inadequacy of such a theory, Humana could not have alleged it because its core allegations are based on matters that were disclosed publicly years ago.

For example, many of Humana's allegations rehash information that Celgene itself publicly disclosed as early as February 2010, and again in March 2011, in its Annual Reports. Specifically, it disclosed that the FTC had opened an investigation of Celgene regarding "requests by generic companies to purchase our patented THALOMID® and REVLIMID® brand drugs" and was evaluating whether there was reason to believe Celgene had "engaged in unfair methods of competition." *See* Exs. 2-3.[7] Indeed, the same issues had been raised by a petition filed with the FDA by generic manufacturer DRL even earlier, in June 2009. *See* Ex. 2 at 7-8 (alleging Celgene had unlawfully refused to supply samples of Revlimid to DRL).

Likewise, Humana would have had knowledge of these claims from complaints (which it now cites) filed against Celgene by Barr, Lannett and Mylan, as described above.[8] As Humana does here, Barr alleged that Celgene had improperly delayed it from coming to market by negotiating an exclusive contract with a potential Barr

[7] Humana cites these very Annual Reports, which are also a matter of public record, in its Complaint. Compl. ¶ 8 n.5. As such, the Annual Reports are properly before this Court, even if Humana did not attach the documents as exhibits to its complaint. *See Schmidt*, 770 F.3d at 249 (district court properly considered, on motion to dismiss, SEC filings that were matters of public record).

[8] *See* Compl. ¶¶ 143 n.57, 188 n.67, 191, 326-327.

supplier[9]—Barr dismissed these claims way back in 2010, when it voluntarily withdrew its ANDA from FDA consideration.[10] As Humana does here, Lannett and Mylan each alleged that Celgene refused to sell samples in order to delay the introduction of generic drugs and to maintain artificially inflated monopoly prices.[11] As to Lannett, Humana simply copies Lannett's allegations that it attempted to gain FDA approval for its safety protocols so as to be able to purchase samples from Celgene,[12] and Lannett's allegations that Celgene refused to sell samples.[13] And as to Mylan, Humana simply copies its allegations that Celgene (1) refused to sell it Thalomid and Revlimid samples,[14] (2) refused to sell such samples to other generic manufacturers,[15] and (3) settled Lannett's antitrust claims regarding Thalomid samples.[16] These stale allegations are the foundation of Humana's Complaint, not filed until 2019.

Of course, neither Celgene's Annual Reports nor the Barr, Lannett and Mylan Complaints started the clock on the statute of limitations for Humana's claims—the

---

[9] *Compare* Compl. ¶¶ 219-231, *with* Barr Compl. ¶¶ 105-138.

[10] Compl. ¶ 334.

[11] *Compare* Compl. ¶¶ 384-386, *with* Lannett Compl. ¶¶ 68-70, *and* Mylan Compl. ¶ 167.

[12] *Compare* Compl. ¶¶ 174-176, *with* Lannett Compl. ¶¶ 36-40.

[13] *Compare* Compl. ¶¶ 181-187, *with* Lannett Compl. ¶¶ 41-63.

[14] *Compare* Compl. ¶¶ 107-167, *with* Mylan Compl. ¶¶ 72-157.

[15] *Compare* Compl. ¶¶ 168-187, 196-206, *with* Mylan Compl. ¶ 8.

[16] *Compare* Compl. ¶¶ 188-195, *with* Mylan Compl. ¶ 8.

claims accrued by the point at which the alleged misconduct first caused the alleged injury, which Humana alleges was in 2006 and 2009, when generic versions of Thalomid and Revlimid allegedly "would have" been available, Compl. ¶¶ 379-380. *See Klehr*, 521 U.S. at 190-91.

But for present purposes, the point is simply that even if Humana could claim that the statute of limitations did not begin to run until an identical theory was laid out in the *Mylan* Complaint in April 2014, Humana *still* waited more than four years to bring its own Complaint containing those allegations, not to mention the many years that passed from the filing of Barr's Complaint, the FTC's investigation, and Celgene's litigation with Lannett. Thus, even if a discovery rule applied here (it does not, *see Mathews*, 260 F.3d at 246 n.8), it still could not save Humana's untimely claims. *See GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 179 (4th Cir. 2007) ("Where a plaintiff knows of a pattern of particular actions that a defendant has taken against him, though the pattern's precise scope might be unclear and its exact legal ramifications uncertain, the plaintiff is on inquiry notice of his claim.").[17]

Even if Humana had adequately pled a violation of the antitrust laws within the

[17] Humana does not plead or make any reference to so-called *American Pipe* tolling, under which in some circumstances the filing of a class action can toll the applicable statute of limitations for putative class members until class certification is denied. *See China Agritech, Inc. v. Resh*, 138 S. Ct. 1800, 1804 (2018). Thus, the filing of *In re Thalomid and Revlimid Antitrust Litigation*, No. 14-cv-06997 (D.N.J.), is irrelevant to the timeliness of Humana's claims. Had Humana wished to seek such tolling, it was required to adequately plead facts demonstrating the doctrine applies and to which claims it would apply. *See, e.g.*, *Maine State Ret. Sys. v. Countrywide Fin. Corp.*, 722 F. Supp. 2d 1157, 1168 (C.D. Cal. 2010). Humana's Complaint failed to do so. In any event, the core of Humana's claims would be barred even if *American Pipe* tolling applied because the alleged injury occurred many years prior, in 2006 and 2009, when Humana claims generics "would have" been on the market. Compl. ¶¶ 379-380.

statute of limitations, the law is clear that it cannot recover for any *ongoing* harm "caused by old overt acts outside the limitations period." *See Klehr*, 521 U.S. at 189. Instead, its claim would be limited to "harm *over and above the harm* that the earlier acts caused." *Id.* at 190 (emphasis added); *see also Midwestern Mach. Co. v. Nw. Airlines, Inc.*, 392 F.3d 265, 270 (8th Cir. 2004) (drawing a "distinction between 'new and independent acts that inflict *new and accumulating injury on the plaintiff*' (which restart the statute of limitations), and unabated inertial consequences of previous acts (which do not)") (emphasis added); *Cable Line, Inc. v. Comcast Cable Commc'ns of Pa., Inc.*, No. 3:16-CV-1000, 2017 WL 4685359, at *10 (M.D. Pa. Oct. 18, 2017) (distinguishing an "overt act of reaffirmation" from an "unabated inertial consequence of a previous act" (internal quotation marks omitted)); *Auraria Student Hous. at the Regency, LLC v. Campus Vill. Apartments, LLC*, 843 F.3d 1225, 1248 (10th Cir. 2016) ("The act [that restarts the statute of limitations] must be more than 'the abatable but unabated inertial consequences of some pre-limitations action.'"). Nowhere does Humana attempt to plead a recoverable injury that is separate and distinct from the injury it alleges was caused by conduct outside the limitations period. Instead, it only attempts to plead a singular injury caused by all of the events described in its Complaint, the vast majority of which are outside the limitations period and not a permissible basis for recovery.[18]

[18] To be sure, the Third Circuit has held injurious acts in furtherance of a *conspiracy* within the limitations period are timely even if they are "reaffirmations of decisions originally made outside the limitations period," *W. Penn Allegheny Health Sys.*, 627 F.3d at 107, and "intentional, concerted inaction" *by co-conspirators* can constitute an injurious act, *see In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d Cir. 1993). But here, where Humana does not plead any conspiracy and the case solely concerns unilateral action, there is no such illegal agreement that can cause

For these reasons, Humana's antitrust claims under federal and state law (First, Second and Third Causes of Action) are untimely and should be dismissed. The same is true of Humana's remaining claims (Fourth and Fifth Causes of Action) predicated on the exact same conduct. *See infra* Part IV.A. Humana's failure to plead a claim that satisfies controlling precedent should result in complete dismissal since the Complaint is overwhelmingly comprised of pre-limitations-period allegations, *see, e.g.*, Compl. ¶¶ 107-151, 157-201, 203-246, 325-338, 345-358, and there is no allegation of "new and accumulating injury" for Celgene to answer or move against.

B. Humana Fails to Sufficiently Plead Its Antitrust Claims.

Even if the Complaint could be construed as attempting to plead an antitrust claim arising from acts within the limitations period, those allegations would fail to state a claim upon which relief could be granted.

1. Humana Fails to Plead an Antitrust Claim on Thalomid.

The only Thalomid-related conduct within the last four years that is even nominally pled is that Celgene's patent infringement lawsuit against Lannett, filed in January 2015, allegedly was a "sham." Compl. ¶ 340. Humana does not plead a single other Thalomid-related act, relating to product samples or anything else, after 2012. *See* Compl. ¶ 213 (alleging Celgene requests for information to generic company Sandoz regarding Thalomid samples in 2012). The claim of a sham suit against Lannett goes nowhere for the simple reason that the suit was successful.

---

continuing injury by simply remaining in force. Further, Humana's state law claims suffer from the additional problem that in 12 states, the continuing violation doctrine is not recognized at all, or is recognized only in limited circumstances that are inapplicable here. *See* Appendix B.

a. Lannett agreed to a settlement with August 2019 entry.

The relevant facts are clear from the Complaint. Lannett filed its ANDA in 2014, and included a so-called Paragraph IV certification that Celgene's patents, the last of which expired in 2023, were invalid or not infringed. Celgene sued Lannett for infringement within the mandated 45-day period, in January 2015. The parties litigated for several years, and in 2017, reached a settlement under which Lannett would not have a license to Celgene's patents until August 2019. *Id.* ¶¶ 339-343.

Humana has not alleged (nor could it) that, in the course of the litigation, the District Court rejected a single one of Celgene's claims. To the contrary, Humana acknowledges that under the settlement, Lannett conceded infringement of certain of Celgene's patents, and took a license to others that would not begin until two years into the future. *Id.* ¶¶ 342-343. That is, the parties compromised between Lannett's ANDA filing in 2014 and Celgene's claim that it could not enter before 2023; and so Lannett will be eligible to enter in the middle of 2019.

On these pleaded facts, where Lannett conceded that it could not market its product for more than four years after it first sought to do so, there is no conceivable way for Humana to claim that Celgene's infringement suit was a "sham." *Wellbutrin*, 868 F.3d at 148. Celgene's suit against Lannett would be actionable by Humana only "***if no reasonable person*** could disagree with the assertions of noninfringement or invalidity in [Lannett's Paragraph IV] certification." *Id.* at 149 (emphasis added). Even had the District Court in *Lannett* "rejected" Celgene's claim, that "does not bear on whether the patent infringement suit was objectively baseless from the outset." *Id.* at 150-51. But here, even that did not happen—none of Celgene's claims against

Lannett was "rejected," and the settlement that Lannett negotiated reflected the strength, not the weakness, of Celgene's patent claims.

"[C]ourts have invariably held that lawsuits terminating in favorable settlement are also objectively reasonable and are not shams." *Toyo Tire & Rubber Co. v. Atturo Tire Corp.*, No. 14 C 0206, 2017 WL 1178224, at *4 (N.D. Ill. Mar. 30, 2017).

> [T]he fact that [Celgene] has obtained settlements involving challenges to the validity of the . . . [p]atents and that these patents have never actually been called into question by a judicial authority, while not dispositive, further undercuts [Humana's] ability to allege objective baselessness, particularly where [Humana] ha[s] not called the settlements themselves into question.

United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Novartis Pharm. Corp., No. 15-CV-12732, 2017 WL 2837002, at *13 (D. Mass. June 30, 2017), *aff'd*, 902 F.3d 1 (1st Cir. 2018). If "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party," such as Humana, "should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003).[19]

Humana attempts to recharacterize the 2017 Celgene/Lannett patent settlement, alleging that it also resolved counterclaims that Lannett had brought against Celgene "alleging monopolization, conspiracy to monopolize, and

[19] Humana alleges in passing that a *different* litigation between Celgene and Lannett, the antitrust suit relating to Lannett's request to purchase samples, was settled in 2011, and that *that* settlement "may have contained anticompetitive terms." Compl. ¶¶ 192-194. Setting aside that "maybe" is not a sufficient pleading, Humana's decision to omit even a "maybe" allegation as to the 2017 patent settlement between the parties confirms it has not even attempted to call the relevant settlement "into question." *Novartis*, 2017 WL 2837002, at *13.

anticompetitive acts, including sham litigation." Compl. ¶ 340. This Court need not credit that allegation, because it is contradicted by the face of Lannett's pleading, which is of public record and is incorporated into Humana's Complaint. *See generally* Am. Answer, Defenses, & Countercls., *Celgene Corp. v. Lannett Corp.*, No. 2:15-cv-00697, Dkt. No. 65 at 25-74 (D.N.J. April 18, 2016) (counterclaiming for declaratory judgments of invalidity, unenforceability, and noninfringement, but nowhere alleging any of the antitrust claims Humana describes). To whatever extent Humana seeks to rehash the allegations of others, it cannot mischaracterize those allegations to survive 12(b)(6) scrutiny of its Complaint.

b. Humana's attacks on the '012 and '745 Thalomid patents fail on their face.

Humana argues in two paragraphs of its 100+ page complaint that two Thalomid patents that Celgene asserted against Lannett were fraudulently obtained: U.S. Patent. Nos. 7,230,012 (the '012 patent) and 7,435,745 (the '745 patent). Compl. ¶¶ 246, 321. The allegations are completely unsubstantiated, and come nowhere near meeting the governing standard for pleading fraud on the PTO.

As noted, an antitrust plaintiff claiming it was harmed by a patentee's supposed fraud has a steep hill to climb under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). It must allege: "1. A false representation or deliberate omission of a fact material to patentability[,] 2. made with the intent to deceive the patent examiner[,] 3. on which the examiner justifiably relied in granting the patent, and 4. *but for* which misrepresentation or deliberate omission the patent would not have been granted." *Remeron*, 335 F. Supp. 2d at 528 (quoting *C.R. Bard,*

Inc., 157 F.3d at 1364). "To establish fraud for purposes of antitrust violation the defendant 'must make a greater showing of scienter and materiality' than when seeking unenforceability based on conduct before the Patent Office." *C.R. Bard, Inc.*, 157 F.3d at 1364 (quoting 6 Donald S. Chisum, *Chisum on Patents* § 19.03[6][e] (rel. 47 1993)). As the Federal Circuit has noted:

> [K]nowing and willful fraud as the term is used in *Walker* can mean no less than clear, convincing proof of intentional fraud involving affirmative dishonesty, a deliberately planned and carefully executed scheme to defraud. . . . Patent fraud cases prior to *Walker* required a rigorous standard of deceit. . . . *Walker* requires no less.

Id. at 1364-65 (ellipses in original) (internal quotation marks omitted). Rule 9(b), in turn, "requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1327. So the burden of proof on Humana—an antitrust plaintiff seeking to collaterally attack the assertion of the patent against another party—is very high.

Humana's bare pleading fails this test. For the '012 patent, Humana does not even identify the specific prior art that Celgene purportedly withheld from the PTO; it simply refers to supposedly "extensive scientific literature," which literature allegedly "establishes the immunomodulatory properties of thalidomide and its derivative, lenalidomide, the active ingredient in Revlimid." Compl. ¶ 245. An inequitable conduct allegation goes nowhere without specific "identif[ication of] what relevant and undisclosed prior art was known to the patentee." *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols., P.C.*, 482 F.3d 1347, 1356-57 (Fed. Cir. 2007).

For the '745 patent, Humana goes no further than disclosing what the

supposedly withheld prior art was—other patents. *See* Compl. ¶ 321. It fails to plead the remaining three elements of inequitable conduct: (2) that the omission was "made with the intent to deceive the patent examiner," (3) that the patent examiner "justifiably relied" on the omission in granting the patent, and (4) that "*but for* which misrepresentation or deliberate omission the patent would not have been granted." *Remeron*, 335 F. Supp. 2d at 528.

This is not merely a pleading deficiency; it compels dismissal. "The heightened standard of materiality in a *Walker Process* case requires that the patent would not have issued *but for* the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 9 (1st Cir. 2018) (internal quotation marks omitted).

Further, these two patents have been litigated twice, for a combined total of nearly seven years of litigation: with Lannett, which agreed to respect the patents until August 2019 (as described above), and before that with Barr (which as described below dropped its patent challenge and its ANDA altogether). "[N]one" of the cases "has been adjudicated in [the opposing party's] favor," which on these patents belies Humana's sham claims. *New W., L.P. v. City of Joliet*, 491 F.3d 717, 722 (7th Cir. 2007) (noting further that "even if [the opposing party] ultimately wins them all, that would not demonstrate that the suits were shams, a term that the Supreme Court has used to denote baseless litigation filed only because of the expense that the defendant must incur"). Indeed, neither Lannett nor Barr even attempted to allege that these patents were obtained through fraud. Humana's allegations are a blatant attempt to distract

from the fact that the outcomes of these patent litigations defeat any suggestion that they were "shams" based on "fraudulent" patents.

c. Humana relies on Barr's withdrawn ANDA to no avail.

Humana includes a series of allegations related to the ANDA that Barr filed for generic Thalomid. Barr filed that ANDA in December 2006, and Celgene commenced its patent infringement suit in January 2007. Compl. ¶¶ 225, 326. Barr counterclaimed in March 2007—and it is those counterclaims that Humana copies in its 2019 Complaint. *Id.* ¶ 327. The parties litigated for three and a half years before Barr withdrew its ANDA from FDA consideration in May 2010, and dismissed with prejudice its counterclaims against Celgene. *See* 07-cv-0286, Dkt. Nos. 157 (D.N.J. May 13, 2010) (informing the Court that on May 5, 2010, Barr sent a letter to the FDA "requesting that FDA withdraw Barr's ANDA"), 160 (dismissal filed May 21, 2010). Humana nevertheless regurgitates Barr's 2007 allegations, but to no avail.

First, Humana vaguely alleges that Barr's withdrawal was related to a "settlement" with Celgene that "may" have been anticompetitive, Compl. ¶¶ 334-338, but none of the settlement terms that "may" have existed are pled. And for good reason—there never was a settlement—Barr withdrew its ANDA, and then separately dismissed its claims against Celgene by stipulation. A vague allegation that there "may" have been an "anticompetitive settlement" nine years ago is meaningless.

Second, Humana copies allegations made by Barr that in 2005, Celgene interfered with a supply contract Barr intended to sign, delaying the filing of its ANDA. As explained above, these allegations were made public in March 2007, and dismissed with prejudice in May 2010. In a 2019 complaint, these allegations are

untimely in the extreme. And they go nowhere: Humana fails to even allege that Barr's withdrawal of its ANDA had anything to do with alleged interference with the supply contract; and any alleged delay in the filing of the ANDA could not possibly have injured Humana given that the ANDA was withdrawn altogether in 2010.

Third, Humana claims that Celgene delayed Barr's ANDA by filing a "baseless" Citizen Petition with the FDA. Compl. ¶¶ 329-30. Given that petition was publicly filed in 2007,[20] it is hard to see how Humana's claims thereon could be timely. The FDA, for its part, never treated the petition as baseless—to the contrary, it waited until 2014 to deny it in part as moot, because Barr had withdrawn its ANDA.[21] In any event, as noted, Barr filed its ANDA before the Citizen Petition was filed and then withdrew its ANDA before it was ruled upon, so there is no conceivable way that Celgene's Citizen Petition delayed Barr from coming to market.

d. Humana's recycling of Barr's challenge to Celgene's REMS patents is irrelevant.

Humana seeks to leverage Barr's 2007 complaint for one additional purpose, one that spans dozens of paragraphs of Humana's Complaint, albeit to no avail. Specifically, Humana borrows, often word for word, Barr's allegations that Celgene's patents on its method of distributing its products safely—the so-called "REMS patents"—were procured by fraud. *Compare* Compl. ¶¶ 252-319 *with* Barr Compl. ¶¶ 35-95 (detailing the *exact same* studies and meetings relied on by Humana, in the

[20] Citizen Petition from Celgene Corp., No. FDA-2007-P-0113 (posted April 28, 2008), https://www.regulations.gov/document?D=FDA-2007-P-0113-0002.

[21] FDA Response to Celgene Corp. Citizen Petition, No. FDA-2007-P-0113 (posted Oct. 1, 2014), https://www.regulations.gov/document?D=FDA-2007-P-0113-0028.

exact same order, often using the *exact same* language).[22] Humana attempts to refresh these stale allegations by pointing to the fact that, in 2016, the PTAB in IPR proceedings invalidated certain claims in two of the patents. Compl. ¶ 253.[23]

This is a red herring, of zero consequence to Humana's claims. The REMS patents have never blocked any generic entry; rather, they have been included in patent infringement suits that separately enforce Celgene's other patents on Thalomid (and Revlimid). Because Humana does not adequately plead that *all* of the patents Celgene asserted against generics were fraudulent, that stops Humana's sham litigation claims in their tracks. The Third Circuit has explicitly rejected the dissection of "sham requests" from "successful requests" within a legal action: "The flaw is in viewing the Petition as [containing] independent requests, rather than as a single petition. When considering whether a petition is entitled to immunity, courts should consider whether the petition as a whole is objectively baseless." *Wellbutrin*, 868 F.3d at 156 n.34.[24] Disputes about the ultimate merits of a party's claim—here, Celgene's assertion of the REMS patents—are "ultimately irrelevant"; the sole question is whether Celgene "could have perceived 'some likelihood of success' in [*its*] *case* at the time of filing."

---

[22] Indeed, Humana lifts several allegations from Barr's counterclaims nearly verbatim. *Compare, e.g.*, Compl. ¶¶ 267 & 294, *with* Barr Compl. ¶¶ 38, 76.

[23] Those rulings are on appeal at the Federal Circuit. *See Celgene Corp. v. Iancu*, Dkt. Nos. 18-1167 & 18-1171 (Fed. Cir.).

[24] *See also In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 312 (E.D. Pa. 2011) ("[C]onduct is not a sham if at least one claim in the [petition] has objective merit.") (second alteration in original) (internal quotation marks omitted)); *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 224 (S.D.N.Y. 2002) (defendants' litigation was not a sham because claims on four of six asserted patents proceeded "beyond summary judgment" and "two of the four" proceeded through trial).

Id. at 150 (emphasis added).

Humana's inability to plead that the REMS patents were the only obstacle to a generic also deprives Humana of antitrust injury. "[A]ny delay caused by [the allegedly sham assertion of REMS patents] is irrelevant—the blocking patent [*i.e.*, the other patents] would have prevented a lawful launch even in the absence of" the assertion of the REMS patents. *Id.* at 156 n.33. In other words, if a generic would infringe even one valid patent claim, a plaintiff has no antitrust injury to complain about the absence of that product—essentially, no standing to sue; it does not matter if other patent claims (even claims that were later invalidated) were also asserted.

e. This Court's partial denial of summary judgment in *Mylan* does not help Humana.

Humana pleads the procedural history of the *Mylan* case, including this Court's partial denial of summary judgment, and the scheduling of the upcoming trial. Compl. ¶ 152. It is as if Humana believes the law permitted it to sit back and to watch the issue be raised to the FDA in a petition filed in 2009; to watch the FTC open an investigation, publicly announced in 2010, into the subject matter of sales of product samples; to watch Lannett's antitrust lawsuit over samples be litigated through 2011; and then to watch Mylan's antitrust suit be litigated from 2014 through 2019—only to then finally decide to file its own claims five months after summary judgment was decided. (Humana also apparently believes it can rely on the partial *denial* of summary judgment without accepting the partial *grant* of summary judgment—with respect to the issue of FDA protocol approval, *see infra*, II.B.2.a.2.) Humana pleads no theory of tolling that would permit such inaction; there is none.

Humana argues that it ought at least be able to sue for alleged injuries that are derivative from those injuries that the Court has permitted Mylan to attempt to establish at trial, *i.e.*, Mylan's inability to launch generic Thalomid in September 2012 after (allegedly) getting FDA approval of its protocols.[25] The problem is that this is not the theory of liability that Humana has pled. Instead, Humana pleads that it should have been able to buy generic Thalomid from Mylan *as early as 2010*. Compl. ¶ 133. The only basis for this assertion are Mylan's arguments—but those are the arguments that the Court rejected when it held that FDA protocol approval was an objectively reasonable requirement, and that Mylan would be limited to its alternative damages theory, in which "Mylan's launch is delayed to Q3 2012 under the assumption that *Celgene does not provide samples until after Mylan gets FDA approval for its safety protocol*." No. 14-2094, Dkt. No. 287 ("SJ Opinion") at 39-40 (emphasis in original) (internal quotation marks omitted).

Moreover, even if Humana could piggyback on the narrowed Mylan claim, it is still untimely. *See supra*, Part I.A. To whatever extent Mylan can argue that its own claim did not arise until April 2010 (four years before Mylan sued in April 2014), Humana's burden is to show that its claims did not arise before June 2014;[26] given that Mylan publicly sued Celgene over the issue of Thalomid samples in April 2014, there is no way Humana could plausibly allege that.

---

[25] Compl. ¶ 132 ("A federal court previously found, based on these facts, that one could reasonably infer 'that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid® or Revlimid® samples after FDA approval of Mylan's study protocols.") (quoting this Court's opinion in *Mylan*)).

[26] This assumes that the operative date of Humana's Complaint filing is June 2018, accounting for the parties' tolling agreement. *See supra*, note 6.

2. Humana Fails to Plead a Valid Antitrust Claim Relating to Revlimid.

As with Thalomid, Humana makes no allegations related to the withholding of Revlimid samples within the statute of limitations; those allegations are stale, dating back to the period 2008-2013. And Humana's claims as to the alleged withholding of Revlimid samples are legally barred for an independent reason: it does not plead that Celgene failed to provide samples after being advised that the generics had FDA protocol approval. The reason Humana does not plead those facts is that they do not exist—the generic manufacturers at issue did not have FDA approval.

Grasping for a timely claim, Humana alleges that every single infringement suit that Celgene has filed on its Revlimid patents, from its 2010 suit against Natco, to six suits filed against other generics between 2016 and 2018, were a "sham." Compl. ¶¶ 322-323. This is an extraordinary overreach, and Humana's Complaint does not bother to back it up. Celgene's patents on Revlimid extend until 2028. Compl. ¶ 242. Several of the patents, including one that does not expire until 2028, have recently been upheld by the PTAB on challenges brought by generic manufacturers,[27] and none of them has ever been invalidated. Their strength has been confirmed by settlements under which generic competitors were not licensed for partial entry until at least 2022 and full entry until 2026. Humana has not plausibly pled its way around these patents, nor could it.

---

[27] *See supra* note 1; *see also* Decision Denying *Inter Partes* Review, *Alvogen Pine Book LLC v. Celgene*, No. IPR2018-01714 (P.T.A.B. Mar. 14, 2019) (denying IPR petition on the '569 patent, which expires in 2023); Decisions Denying Institution of Inter *Partes* Review, *Dr. Reddy's Laboratories, Inc. v. Celgene Corporation*, Nos. IPR2018-01504, IPR2018-01507, IPR2018-01509 (P.T.A.B. Feb. 11, 2019) (denying IPR petitions on the '120, '717 and '740 patents, which expire in 2023).

a. Humana's Revlimid sample claims fail to state a claim.

1) The Revlimid sample claims are untimely.

Humana alleges Celgene should have sold Revlimid samples to five generic at various points all far outside of the limitations period: DRL in 2008 and 2009, Watson Laboratories ("Watson") in 2009, Teva Pharmaceuticals USA ("Teva") in 2009, Sandoz Inc. ("Sandoz") in 2012, and Mylan in 2013. *See* Compl. ¶¶ 100, 139.

These allegations are untimely on their face for the same reason as with respect to its claims as to withholding of Thalomid samples: Humana has known of all this since DRL made allegations on precisely the same issues—including its own request for samples—in a petition to the FDA in June 2009; since an FTC investigation regarding "requests by generic companies to purchase [Celgene's] patented THALOMID® and REVLIMID® brand drugs" was disclosed in 2010; and since Lannett and Mylan sued Celgene on the same allegations. *See supra* Part I.A. The law is clear that Humana cannot revive these stale allegations on the basis of nothing more than a claim to "continuing injury" more than a decade later—certainly not without some allegation of new anticompetitive conduct and new injury, neither of which Humana can muster. *See supra* Part I.A. If, as Humana alleges, it truly expected to see generic Revlimid on the market "as early as 2009 or 2010," Compl. ¶ 380, then it had no basis to sleep on its claims until 2019.

2) Humana fails to allege that the requesters had FDA protocol approval.

Humana's claims relating to Revlimid samples also fail because it has not alleged that the companies to whom it claims Celgene should have sold Revlimid

samples actually obtained FDA approval of their safety protocols. As this Court held, "Celgene had an objectively legitimate business justification for requiring FDA approval of study protocols before turning over Revlimid® samples," and thus cannot be held liable under section 2 of the Sherman Act prior to such approvals. SJ Opinion at 18, 22-23, 39.

Humana is well aware of the Court's ruling—it affirmatively cites and relies on the Court's summary judgment opinion. *E.g.*, Compl. ¶ 39 n.15, ¶ 152. And Humana goes out of its way to plead that some (though not all) requesters *of Thalomid* had FDA approval of those protocols; Humana well understands that this is a legal prerequisite to its antitrust claims no different than it was to Mylan's. *See, e.g.,* Compl. ¶ 126 (alleging Mylan had FDA approval of its Thalomid protocols in 2007); ¶ 190 (alleging same for Lannett as of 2008).

Yet, as if to glide past this issue with respect to Revlimid, Humana instead alleges that the Revlimid requesters "assured Celgene any testing [they] performed would comply with FDA guidelines." Compl. ¶ 199 (DRL); *see also id.* ¶¶ 204 (Teva), 208 (Watson).[28] Humana goes no further than to allege that the requester provided Celgene with assurances that it *would* obtain approval for its safety protocols, not that they *had* obtained such an FDA approval. In the absence of such an allegation, Humana has failed to allege that Celgene acted without an objectively reasonable business justification in any refusal to sell Revlimid samples to these companies.

[28] As to Sandoz, Humana does not even allege this much. Instead, it makes a vague reference to "FDA approval of Sandoz's procedures." Compl. ¶ 216. Humana makes no allegation that the FDA approved Sandoz's Revlimid safety protocols, much less that Celgene was so informed by Sandoz (it was not).

Humana's allegations as to *Mylan's* request for Revlimid present a slightly different issue. As the Court held, "Celgene had an objectively legitimate business justification for requiring FDA approval of study protocols before turning over Revlimid® samples. And Mylan did not seek Revlimid® samples from Celgene and get FDA approval of its protocols until 2013—and did not communicate said FDA approval to Celgene until 2014." SJ Opinion at 39. Mylan argued that it should nonetheless be able to recover on a theory that it "would have" purchased Revlimid samples from Celgene in 2008, but the Court rejected this theory, explaining, *inter alia*, that "Mylan does not point to any evidence that Mylan could have developed its study protocols for its lenalidomide ANDA sooner than it actually did." *Id.* at 39-40.

Humana is careful not to regurgitate that rejected theory, but it does allege (citing the same Mylan expert report that failed to aid Mylan) that Mylan could somehow have filed a Revlimid ANDA way back in 2009. Compl. ¶ 154. That allegation fails for two reasons. *First*, to the extent Humana is relying on the same evidence and theory that Mylan relied on, that route failed for Mylan, and Humana cannot plausibly allege it would have bought a Mylan generic product earlier than Mylan can establish it would have been selling it. *Second*, in the *Mylan* case, Mylan's position was that it would have first begun selling a generic Revlimid product in 2022. SJ Opinion at 36, 38-39. Mylan conceded, due to Celgene's Revlimid patents, that it could not have started selling such a product any earlier. Humana's allegation that Mylan would have entered earlier than Mylan itself claimed was possible is not plausible and, therefore, need not be credited. *Twombly*, 550 U.S. at 555-56.

b. Humana's claims of sham litigation on the Revlimid patents fails to state a claim.

In an attempt to get past the facial untimeliness of its samples claims, and to come up with some timely claim to damages on Revlimid, Humana alleges that every single one of the patent infringement suits that Celgene has filed against six companies that have filed ANDAs to market generic Revlimid are "shams."[29] The only allegations that Humana offers in support of this sprawling attempt to relitigate six different litigations is that *one* of thirteen Celgene patents on Revlimid[30] was procured by "fraud," and certain of its other patents to polymorphs of the compound are "generally not separately patentable." These shotgun allegations cannot prop up Humana's Complaint.

1) Natco Pharma.

Natco, the first generic to file an ANDA for Revlimid, litigated Celgene's Revlimid patents for five years (from 2010-2015), only to negotiate a settlement under which it has a patent license to sell a limited quantity beginning in 2022, and an unlimited license that does not begin until 2026. Compl. ¶ 357. Because the patents that Celgene asserted against Natco expire one year later, in 2027, *id.*, this was virtually a complete vindication of Celgene's patent infringement claims.

The terms on which Natco settled its challenge to Celgene's patents put to rest any claim of sham litigation. How could Humana conceivably show that "no

[29] Compl. ¶¶ 345-358 (sham litigation against Natco); Compl. ¶¶ 359-361 (sham litigation against DRL); Compl. ¶¶ 362-365 (sham litigation against Zydus); Compl. ¶¶ 366-69 (sham litigation against Cipla); Compl. ¶¶ 370-373 (sham litigation against Alvogen); Compl. ¶¶ 374-377 (sham litigation against Sun).

[30] Humana pleads that Celgene has thirteen patents on Revlimid, Compl. ¶ 96; while there are additional such patents, that is of no moment for present purposes.

reasonable litigant [in Celgene's shoes] could realistically expect success on the merits," when Celgene in fact succeeded? *Wellbutrin*, 868 F.3d at 148 (internal quotation marks omitted). Or, from Natco's perspective, how could Humana show that "no reasonable person could disagree with [Natco's] assertions of noninfringement or invalidity," given that Natco walked away from them and agreed to wait until nearly all of the patent life expires before fully launching its product? *Id.* at 149. Humana cannot so plead. Whatever Humana seeks to make of its recitation of some of the arguments Natco had made, Compl. ¶¶ 349-356, Humana concedes that Natco walked away from those, and settled the case on terms favorable to Celgene. There is no plausible way for Humana to allege that Natco would have been selling a generic product years earlier in the absence of "sham" litigation by Celgene.

2) Other patent infringement suits.

Humana also alleges that other patent suits Celgene filed from 2016-2018, against various Revlimid ANDA filers, were shams. *Supra*, note 29. Humana's pleading of these claims is exceedingly bare: it does nothing other than to summarize the procedural history of the cases, which are all in varying stages.[31] These claims can be dismissed for two independent reasons.

First, Humana does not allege that any rulings were adverse to Celgene in these cases, or a single other reason to think that the suits were "objectively baseless in the

[31] One of the remaining Revlimid ANDA litigants, Alvogen, announced (after the filing of Humana's Complaint) a settlement with Celgene, under which Alvogen cannot begin selling its product until after Natco's limited entry date. *See* https://alvogen.com/newsroom/alvogen-settles-u-s-revlimid-r-patent-litigation-with-celgene.

sense that no reasonable litigant could realistically expect success on the merits." *Wellbutrin*, 868 F.3d at 148 (internal quotation marks omitted). As with the Natco allegations, Humana's allegations as to these five cases, all against generics who filed ANDAs with Paragraph IV certifications challenging Celgene's patents, are incurably deficient under the Third Circuit's articulation of the standard for such claims:

> The already high hurdle for stating an antitrust claim for anticompetitive litigation, is ***higher still in the context of an ANDA case*** because, as described above, the Hatch-Waxman Act states that "[i]t shall be an act of infringement to submit" an ANDA for a drug claimed in a patent, 35 U.S.C. § 271(e)(2). Since the submission of an ANDA is, by statutory definition, an infringing act, an infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification.

Id. at 149 (emphasis added) (citation omitted).

Second, Humana does not (nor could it) connect these lawsuits to any alleged harm to Humana. Humana fails to allege that but for these litigations, any of these companies—who filed ANDAs only in the last few years—would have been able to launch generic Revlimid and sold it to Humana at some time in the past. Humana therefore cannot plausibly claim to have somehow been injured by the litigations against these ANDA filers.

3) Celgene's patent on the compound in Revlimid precludes any antitrust injury to Humana.

Without a way around the Natco settlement or Mylan's concession that it could not have done any better in a challenge to Celgene's patents, and without any specific allegations as to precisely why Celgene's patent litigations against Revlimid ANDA filers were so frivolous that "no reasonable litigant could realistically expect success,"

Humana attempts a fly-by attack on one of Celgene's Revlimid patents, No. 5,635,517 (the '517 patent). Humana claims it was procured by fraud on the PTO. Compl. ¶¶ 244-245. The allegation is not simply unsubstantiated; it is frivolous.

As an initial matter, it is plain that the reason that Humana even attempts to brand the '517 patent a fraud in a complaint that is otherwise principally about withholding product samples is simple: the law in the Third Circuit stops all antitrust claims in their tracks when a patent would have prevented the sale of the generic product at issue. "It is not enough for [Humana] to show that [any generic] wanted to launch its drug; they must also show that the launch would have been legal." *Wellbutrin*, 868 F.3d at 165. Humana cannot recover damages for the inability to buy an unlawful, infringing product.

The other reason Humana has to come up with some way to label the '517 patent a "fraud" is that absent such a claim, there is no way for Humana to show that infringement suits against Revlimid ANDAs, all of which were filed years before the October 2019 expiry of the '517 patent, were all sham litigations. The '517 patent covers the compound lenalidomide, which Celgene scientists invented; any generic equivalent would have to contain that compound—there is no "inventing around" it. And yet, since the 1982 establishment of the U.S. Court of Appeals for the Federal Circuit, only a single patent claiming a new chemical compound has ever been invalidated on obviousness grounds.[32] The suggestion that Humana will be the first to prove the '517 patent not only invalid but an outright fraud, with a few months to go before its expiry, is farfetched.

[32] *See Bristol-Myers Squibb Co. v. Teva Pharma. USA, Inc.*, 752 F.3d 967 (Fed. Cir. 2014).

That is not to say that no one has tried to invalidate the '517 patent—only that Humana has not pled any facts to suggest it can succeed where others failed. Natco argued the patent was invalid, but then reached a settlement with Celgene that conceded Natco could not come to market until longer after the '517 patent is to expire. Compl. ¶¶ 346, 357. Then Mylan looked at the patent, and conceded it too could not get it around it, and would not have been able to do better than Natco's settlement. SJ Opinion at 36, 39.

Celgene has also successfully defended the patent in challenges brought before the PTAB. Third parties unsuccessfully petitioned the PTAB to revoke it through an IPR; in a decision published in 2015, the PTAB refused to even open (or to "institute") such a review. Despite the fact that the petitioners' burden in that proceeding was a lower, preponderance-of-the-evidence standard, the PTAB found no "reasonable likelihood that [the challenger] would prevail in showing the unpatentability of any claim" of the patent. *See* Ex. 1, at 2.[33] The PTAB's standard was far lower than the "clear and convincing evidence" that a generic seeking to invalidate a patent (such as Natco) is held to in District Court. And, critically for purposes of an antitrust claim such as Humana's, the PTAB's lower standard is the polar opposite of the heightened, *Walker Process* standard that Humana must meet here to show not only clear and convincing evidence of invalidity, but to prove the four elements of a claim that Celgene defrauded the PTO into thinking otherwise. *See supra*, I.B.1.b.

[33] The petitioner challenged the '517 patent on the same ground asserted in Humana's Complaint—that pre-existing knowledge relating to *thalidomide* made the innovations in lenalidomide obvious—and the PTAB rejected that contention.

That standard is extraordinarily high, and after two paragraphs in its Complaint, Humana gives up trying. Humana asserts only that "[e]xtensive scientific literature establishes the immunomodulatory properties of . . . lenalidomide, the active ingredient in Revlimid," and that the '517 patent is "obvious in light of the innovations and research conducted long before Celgene began its efforts to bring . . . Revlimid to market." Compl. ¶¶ 244-245. Exactly what "extensive scientific literature," and exactly what "innovations and research," Humana does not say.

A more cursory pleading would be hard to imagine; this is exactly the sort of "conclusory statement[]," *Iqbal*, 556 U.S. at 678, that fails to get Humana even past the pleading standard of Rule 8. It comes nowhere near the Rule 9(b) threshold for an allegation of fraud. Humana's burden is even "greater" in this context, *C.R. Bard*, 157 F.3d at 1364, because it is required to plead with particularity a *knowing and willful* fraud. *Id.* at 1364-65. Humana makes no attempt at all to do so.

4) Humana's attack on the polymorph patents is insubstantial.

Celgene holds additional patents relating to Revlimid lasting until 2028, Compl. ¶ 242, and Humana does not allege that they were obtained fraudulently, or that litigation relating to them is a "sham." The only shot that Humana takes is to argue that a certain subset of patents on "polymorphs" are "generally not separately patentable." *Id.* ¶ 247. Where exactly that takes Humana, it does not say. It certainly does not take it all the way to a claim that Celgene had or has no reasonable expectation of success in any of its litigations, which are not limited to such "polymorph" patents; the face of Humana's Complaint lists the several other patents

that cover Revlimid. *Id.* ¶ 96.

In any event, Humana's legal argument that polymorphs "generally are not separately patentable" is contrary to law. The Federal Circuit, which has explained that "[a] polymorph is a chemical compound that can present in different three-dimensional crystalline structures," has upheld the validity of such patents in the face of an obviousness challenge. *See Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1336 n.1, 1344-45 (Fed. Cir. 2019). As some commentators have noted, after *Grunenthal*, "ANDA filers should expect that already difficult obviousness challenges to polymorph patents will be even more difficult." Luke T. Shannon & Taras A. Gracey, *Federal Circuit Addresses Obviousness of Polymorphs in* Grunenthal GmbH v. Alkem Labs. Ltd.*, No. 2017-1153 (Fed. Cir. Mar. 28, 2019)*, Nat'l L. Rev. (Apr. 4, 2019). If Humana sought to prove that polymorphs are "generally not separately patentable," it would need to do more than simply announce it.

II. Humana's Attempt to Sue on Behalf of Unidentified Plans Violates Rule 10 and Procedural Due Process.

Humana purports to bring claims in several different capacities, which matters for purposes of the Court's antitrust analysis.

Under federal antitrust law, only direct purchasers—essentially, those in privity with the defendants—can bring damages claims. Under the "*Illinois Brick* doctrine," established in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), indirect purchasers lack standing to bring antitrust claims for damages. The only Humana affiliate that alleges such "direct purchases" is Humana Pharmacy, Inc., which seeks recovery for purchases made directly from Celgene under Section 2 of the Sherman Act. These

claims fail as a matter of the law for the reasons articulated above.

Humana's insurance arm, by contrast, does not purchase anything from Celgene, or indeed, anything at all; it simply reimburses patients for their purchases. It therefore has no federal damages claim. So, Humana purports to sue under various theories of state law liability, relying on the same alleged conduct, and even purporting to seek double recovery for the same "purchases," that Humana alleges it incurred as a direct purchaser. These claims rest on the same conduct as Humana's federal claims, and so fail for those same reasons described above, in addition to various reasons rooted in applicable state law, described *infra* in Parts III and IV.

But Humana does not stop there. It also purports to bring claims in yet a third capacity: as an administrator of health benefits for its members and group customers. Compl. ¶ 20. Although Humana asserts that it seeks recovery for these customers, it does not identify a single one of the purported customers on whose behalf it administers such claims. The Court should dismiss these claims for two independent reasons.

First, such threadbare allegations run afoul of Fed. R. Civ. P. 10, which requires identification of all the parties. "The purpose of Rule 10(a) is to provide 'clear notice as to the parties in an action.'" *E.E.O.C. v. Int'l Ass'n of Bridge, Structural & Ornamental Ironworkers, Local 580*, 139 F. Supp. 2d 512, 525 (S.D.N.Y. 2001) (quoting *Rosasa v. Judson River Club Rest.*, 1997 WL 316719, at *2 (S.D.N.Y. June 10, 1997)). "The caption, pleadings, service of process and other indications of the intent of the pleader, are evidence upon which a district court will decide, in cases of doubt, whether an entity has properly been made a party to a lawsuit." *Id.* (quoting

Nationwide Mut. Ins. Co. v. Kaufman, 896 F. Supp. 104, 109 (E.D.N.Y. 1995)).

Rule 10 serves a fundamental purpose of allowing defendants to know whose claims are being adjudicated such that they can later be bound by the Court's rulings. In the present posture, for example, no entity whose interests are being asserted by paragraph 20 of Humana's Complaint would be bound by an adverse ruling on Celgene's motion, and they could choose to identify themselves—or not—depending on how Humana's claims progress. *Id.* Humana's allegations are so vague that it could be suing on behalf of thousands of unidentified parties. These claims must be dismissed insofar as it is unclear who Humana is suing on behalf of.

Second, although Humana claims it has arrangements with these unspecified health insurance plans, it serves as a mere *administrative* service provider. Thus, in addition to failing to identify *which* plans it seeks to include here, Humana fails to suggest (much less specifically plead) it has legal *authority* to actually file a lawsuit on their behalves. Humana cannot satisfy that authority requirement by cursorily pleading that they "contract with Humana to administer claims on their behalf and pursue recoveries related to those claims." *Id.* ¶ 20.

Celgene contends that Humana does not state any claims for the reasons explained in Part I. But to whatever extent the Court holds otherwise, it should still dismiss claims that Humana purports to bring on behalf of absent and unnamed parties; there is no justification in the law for Humana to pursue such a stunt.

III. Humana's State Antitrust Claims Must be Dismissed on Additional Grounds.

Humana alleges monopolization and attempted monopolization under the laws

of twenty-five states, the District of Columbia, and Puerto Rico. Compl. ¶¶ 414-424 (Counts II and III). In addition to the grounds to dismiss the entire Complaint set forth in Part I, all of these claims should be dismissed for lack of standing and for failure to satisfy state-specific requirements.

A. Humana's Indirect Purchaser Claims Are Too Attenuated to Establish Standing.

To pursue an antitrust claim, a plaintiff must first have standing to do so. Courts evaluating antitrust standing must consider a number of discrete factors, including the directness of the injury, the existence of more-direct victims who would be more efficient enforcers of the antitrust laws, and the potential for duplicative recovery. *See Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 232-33 (3d Cir. 2013). Here, Humana alleges Celgene violated the antitrust laws by refusing to sell product samples to competitors, and by enforcing fraudulent patents in "sham litigations." But there is no question that more-direct alleged victims are available to assert such claims (and many have): Mylan and other prospective competitors have brought suit based on the same core allegations in Humana's Complaint. Humana's far-more-attenuated theory as an insurer/indirect purchaser is that ***if*** *those entities* (1) had obtained samples of Thalomid and Revlimid earlier, (2) developed and obtained FDA approval for generic alternatives, (3) successfully challenged Celgene's Thalomid and Revlimid patents, and (4) priced their generic alternatives substantially lower than Celgene's prices, then yet *other entities* (*i.e.*, the nation's pharmacies, including in some instances Humana's in-house pharmacy as a direct purchaser) would have paid less for these drugs, and only then would Humana's insurance arm

have paid less in reimbursement.

Faced with similar daisy-chain theories of liability, several courts have held that such claims are inappropriate as a matter of law. For example, in *In re K-Dur Antitrust Litigation*, the court dismissed the plaintiffs' claims, concluding:

> Clearly, the boundaries of standing, even in the context of antitrust claims of monopolization based upon *Walker Process*-type allegations, simply cannot be stretched as far as the Plaintiffs would have this Court extend them. If this Court were to conclude that *indirect* purchasers had standing to bring *Walker Process* claims, it would turn antitrust policy on its head, and extend antitrust standing to an extraordinary level. . . . I do not believe that antitrust policy or patent law contemplates a scenario in which parties only tangentially affected by a patent holder's suit to enforce a patent against its competitors, regardless of whether the patent was fraudulently procured, which is ultimately settled by the original litigants, may be relitigated by consumers or indirect purchasers.

No. 01-1652 (JAG), 2007 WL 5297755, at *18 (D.N.J. Mar. 1, 2007); *see also Farag v. Health Care Serv. Corp.*, No. 17 C 2547, 2017 WL 2868999, at *5 (N.D. Ill. July 5, 2017) ("Plaintiffs are *indirect* purchasers with respect to Novartis, and courts confronted with such situations decline to find *Walker Process* standing."). This Court should reach the same result because Humana's indirect purchaser claims are too attenuated from the *Walker Process* and sham litigation allegations to efficiently enforce the antitrust laws.

B. Humana Is Not a Proper Plaintiff under Certain States' Laws.

Humana's antitrust claims under the laws of Florida and Massachusetts are barred because those states follow *Illinois Brick*, which "held that indirect purchasers lack Article III standing to assert federal antitrust claims against manufacturers." *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 391 (D.N.J. 2018) (citing *Illinois Brick*, 431 U.S. at 726-27); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 160-61 (E.D.

Pa. 2009) (prohibiting indirect claims in Florida); *see also Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, No. 15 CIV. 6549, 2018 WL 7197233, at *22-23 (S.D.N.Y. Dec. 26, 2018) (prohibiting indirect claims in Florida and Massachusetts). Similarly, Humana cannot assert an antitrust claim under Rhode Island law based on conduct before July 15, 2013—the day that Rhode Island enacted a repealer statute. *Effexor*, 357 F. Supp. 3d at 392.

C. Humana Fails to Allege Specific In-State Impacts.

The antitrust laws of New York, Tennessee, and Wisconsin require allegations that the anticompetitive conduct affected *intra*state commerce. "Where the conduct complained of principally affects interstate commerce, with little or no impact on local or intrastate commerce, it is clear that federal antitrust laws operate to preempt the field and oust state courts of jurisdiction." *H-Quotient, Inc. v. Knight Trading Grp., Inc.*, No. 03 CIV. 5889 (DAB), 2005 WL 323750, at *4 (S.D.N.Y. Feb. 9, 2005) (internal quotation marks omitted); *see Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 523 (Tenn. 2005) (requiring "substantial effects" on intrastate commerce); *Olstad v. Microsoft Corp.*, 700 N.W.2d 139, 158 (Wisc. 2005) (same).

Certain consumer protection statutes also require "that Defendants' unlawful conduct affect trade and commerce in the state under whose law they are suing." *See In re Magnesium Oxide Antitrust Litig.*, No. 10-5943 (DRD), 2011 WL 5008090, at *25 (D.N.J. Oct. 20, 2011). In such states, conclusory allegations that fail to tie "injuries to the alleged conspiracy's effect on trade and commerce in those specific states" warrant a dismissal for lack of standing. *Id.* at *26. Humana's failure to make a single specific, non-conclusory allegation regarding intrastate conduct warrants dismissal of

its consumer protection allegations in Massachusetts, North Carolina, South Carolina, Nebraska, New Hampshire, New York, and Vermont.[34]

IV. Humana's Consumer Protection Claims and Unjust Enrichment Claims Must Be Dismissed in Their Entirety.

Humana also purports to assert—based on the same alleged anticompetitive conduct—claims under the consumer protection statutes of thirty-three states and the District of Columbia, Compl. ¶¶ 425-428 (Count IV), and claims for unjust enrichment under the laws of all states, territories, and the District of Columbia, except Ohio and Indiana, Compl. ¶¶ 429-440 (Count V). These Counts too should be dismissed for failure to state a claim for the reasons explained in Part I. They should be dismissed for the additional reasons that Humana (a) asserts untimely claims, (b) fails to satisfy basic pleading requirements, and (c) otherwise fails to the state a claim under certain states' laws.

A. Humana's Consumer Protection and Unjust Enrichment Claims are Untimely.

As discussed in Part I, Humana's Complaint focuses on alleged conduct occurring and causing injury a decade or more ago, about which others previously made public allegations over the last decade. And as Humana's antitrust claims are untimely, so too are its consumer protection claims and unjust enrichment claims.

Like Humana's antitrust claims, the overwhelming majority of its consumer

[34] *See Magnesium Oxide*, 2011 WL 5008090, at *25-26 (dismissing similarly conclusory allegations in Massachusetts, South Carolina, Nebraska, New Hampshire, and New York); *Merck & Co. v. Lyon*, 941 F. Supp. 1443, 1463 (M.D.N.C. 1996) (NCTPA claims must allege "a substantial effect" on in-state operations); *Sherman v. Ben & Jerry's Franch., Inc.*, No. 1:08-CV-207, 2009 WL 2462539, at *9 (D. Vt. Aug. 10, 2009) (out-of-state plaintiffs alleging out-of-state conduct lack standing under the VCFPA).

protection claims are subject to statutes of limitations of four or fewer years,[35] and should be dismissed for the reasons set forth in Part I. Even in states with longer statute of limitations,[36] the alleged conduct and alleged injury falls outside those limitations periods and should be dismissed for the reasons previously articulated.

Because Humana's unjust enrichment, state antitrust, and consumer protection claims are premised on the same alleged misconduct, the Court should apply the statutes of limitations applicable to those statutory claims and dismiss the unjust enrichment claims as well. *See, e.g.*, *GEICO Corp. v. Autoliv, Inc.*, 345 F. Supp. 3d 799, 835 (E.D. Mich. 2018) (applying state antitrust and consumer protection statute of limitations to unjust enrichment claims based on same conduct). However, even if the Court were to apply the state-specific statutes of limitations for unjust enrichment, Humana's claims remain untimely because the majority of its claims are subject to a limitations period of four or fewer years, and even those subject to longer statutes of limitations are also untimely.[37]

---

[35] ***Four*** states impose a one-year limitations period: Arizona, Louisiana, Oregon, and Wyoming. ***Four*** impose a two-year limitations period: Idaho, Indiana, Utah, and Virginia. ***Nine*** impose a three-year limitations period: Colorado, the District of Columbia, Illinois, Kansas, Mississippi, New Hampshire, New York, South Carolina, and Wisconsin. ***Ten*** impose a four-year limitations period: California, Florida, Massachusetts, Minnesota, Nebraska, Nevada, New Mexico, North Carolina, South Dakota, and West Virginia. *See* Appendix A.

[36] Arkansas (5 years), Maine (6 years), Michigan (6 years), Missouri (5 years), North Dakota (6 years), Pennsylvania (6 years), and Vermont (6 years). *See* Appendix A.

[37] Puerto Rico imposes a one-year statute of limitations. *See* P.R. Laws tit. 31 § 5298. ***Three*** states have two-year statute of limitations: Oklahoma, Oregon, and Texas. ***Nineteen*** states impose a three-year limitations period: Alaska, Arkansas, California, Colorado, Delaware, the District of Columbia, Kansas, Maryland, Massachusetts,

Where state law applies laches instead of a statute of limitations, Humana's claims should still be dismissed. In West Virginia, unjust enrichment claims may be barred if the plaintiff's failure to timely claim injury prejudices the defendant. *See Dunn v. Rockwell*, 689 S.E. 2d 255, 267 n.11, 273 n.18 (W. Va. 2009). Here, Celgene relied to its detriment on a business relationship with Humana—Humana alleges a contractual relationship with Celgene beginning in August 2010, Compl. ¶ 18—when the facts underlying Humana's challenge to that relationship have been public for years. *See Joint Stock Soc'y v. UDV N. Am., Inc.*, 53 F. Supp. 2d 692, 717 (D. Del. 1999) ("Economic prejudice arises when a defendant. . . incur[s] significant monetary penalties as a result of conduct which could have been altered by an earlier lawsuit.").

B. Humana Fails To Satisfy Rule 8 Pleading Standards.

Humana's conclusory and threadbare allegations of consumer protection violations and unjust enrichment, Compl. ¶¶ 425-440, do not provide "a short and plain statement of the claim showing that [Humana] is entitled to relief." Fed. R. Civ. P. 8(a). For example, Humana merely states that "Celgene has engaged in unfair competition or deceptive acts and practices in violation of the following state laws" and then lists various state statutes. Compl. ¶ 428. Dismissing similar allegations in *In re Opana ER Antitrust Litigation*, the court noted "[t]he bald assertion that the alleged antitrust conduct violates dozens of non-antitrust laws, or the implication that there

---

Mississippi, Montana, New Hampshire, New York, North Carolina, Rhode Island, South Carolina, Tennessee, Virginia, and Washington. ***Ten*** states impose a four-year limitations period: Arizona, Florida, Georgia, Idaho, Nebraska, Nevada, New Mexico, Pennsylvania, Utah, and Wyoming. ***Four*** states impose a five-year limitations period: Illinois, Iowa, Kentucky, and Missouri. ***Eleven*** states impose six-year limitation period: Alabama, Connecticut, Hawaii, Maine, Michigan, Minnesota, New Jersey, North Dakota, South Dakota, Vermont, and Wisconsin. *See* Appendix A.

are no consequential differences between those laws, is not entitled to deference, because 'the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.'" 162 F. Supp. 3d 704, 726 (N.D. Ill. 2016) (quoting *Iqbal*, 556 U.S. at 678)); *see also In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 255-56 (D. Conn. 2015) (rejecting similar claims because plaintiffs cannot list "state-law claims for states where they might otherwise have no available antitrust recovery and rely on the defendants and the court to sort out whether or how those laws can act as surrogates for antitrust law"). Counts IV and V must be dismissed.

C. Humana Fails to State a Claim Under State Law.

Humana's Complaint is also deficient on state-specific grounds as well.

1. Humana's Consumer Protection Claims Do Not Satisfy Additional Requirements in Twelve Jurisdictions.

Humana's failure to satisfy the below additional requirements for consumer protection claims warrants dismissal of its claims in the following states:

- California: A plaintiff must plead "actual reliance" under the California Unfair Competition Law. *In re Tobacco II Cases*, 207 P.3d 20, 39 (Cal. 2009). Humana does not do so.
- District of Columbia: The D.C. consumer protection statute only covers "the ultimate retail transaction between the final distributor and the individual member of the consuming public." *Sergeants Benevolent*, 2018 WL 7197233, at *39. Humana is neither. Moreover, "the CPPA . . . does not apply to commercial dealings outside the consumer sphere." *Id.*
- Illinois: The Illinois Consumer Fraud and Deceptive Businesses Act is inapplicable to antitrust conduct such as alleged by Humana. *See Laughlin v. Evanston Hosp.*, 550 N.E.2d 986, 993 (Ill. 1990).
- Kansas: The Kansas Consumer Protection Act requires pleading "deception." *Sergeants Benevolent*, 2018 WL 7197233, at *43. Humana does not do so. Further, Humana is not a "consumer" within the statute's definition. Kan. Stat.

Ann. § 50-624(b).

- Louisiana: Even if "Louisiana's law redundantly allows the same antitrust claim to be brought under multiple laws, the *Illinois Brick* rule [precluding indirect purchaser claims] will nevertheless apply until an authoritative statement of Louisiana's legislature or courts says otherwise." *Aggrenox*, 2016 WL 4204478, at *4.

- Maine: Humana did not make any purchases "primarily for personal, family, or household purposes," as required by statute. Me. Rev. Stat. tit. 5, § 213; *Sergeants Benevolent*, 2018 WL 7197233, at *43.

- Missouri: Missouri's law "confer[s] standing exclusively on those who purchase property for their own use." *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 355 F. Supp. 3d 145, 157 (E.D.N.Y. 2018) (collecting cases). Humana cannot so plead.

- New York: "[A]nticompetitive conduct that is not premised on consumer deception is not within the ambit of the [The New York consumer protection] statute," because "[t]he statute seeks to secure an honest market place where trust, and not deception, prevails." *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 410 (S.D.N.Y. 2011) (citations and quotation marks omitted). Humana does not plead it was deceived, nor that it is a consumer.

- Pennsylvania: A plaintiff must make a "showing of justifiable reliance, not simply a causal connection between the misrepresentation and the harm." *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 222 (3d Cir. 2008); *Restasis*, 355 F. Supp. 3d at 160; *See In re Static Random Access Memory (SRAM) Antitrust Litig.*, 580 F. Supp. 2d 896, 909 (N.D. Cal. 2008). Humana makes no such pleading.

- Tennessee: Tennessee's Consumer Protection Act statute prohibits recovery for alleged anticompetitive conduct. *Bennett v. Visa U.S.A. Inc.*, 198 S.W.3d 747, 755 (Tenn. Ct. App. 2006); *see also Sergeants Benevolent*, 2018 WL 7197233, at *49 (collecting cases).

- Utah: Utah law only prohibits "deceptive act[s]," Utah Code Ann. § 13-11-4, and "unconscionable act[s]," *id.* § 13-11-5, enumerated in the statute, which does not contain antitrust violations. *See In re Dynamic Random Access Memory (Dram) Antitrust Litig.*, 516 F. Supp. 2d 1072, 1117 (N.D. Cal. 2007).

- Vermont: Under Vermont law, only "consumers" can bring an action, Vt. Stat. Ann. tit. 9, § 2461(b), and Humana does not meet the statutory definition of a consumer, *see id.* § 2451(a); *see also Restasis*, 355 F. Supp. 3d at 161.

2. Humana Cannot Plead Unjust Enrichment as an End Around State Laws that Bar Indirect Purchasers Suits.

Humana's unjust enrichment claims are also an impermissible attempt to circumvent state antitrust and consumer protection laws prohibiting indirect purchasers from maintaining a cause of action. "[T]he vast majority of courts rightly hold that unjust enrichment may not supply a valid cause of action in states where plaintiffs are otherwise barred from recovery under relevant antitrust and consumer protection statutes." *In re Packaged Seafood Prod. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1088 (S.D. Cal. 2017); *see also In re K-Dur Antitrust Litigation*, No. CIV.A. 01-1652 (JAG), 2008 WL 2660780, at *5 (D.N.J. Feb. 28, 2008) ("[W]here the applicable state law bars antitrust actions for damages by indirect purchasers, or simply does not recognize a private cause of action for antitrust violations, a plaintiff cannot circumvent the statutory framework by recasting an antitrust claim as one for unjust enrichment."). Humana concedes by omission that *Illinois Brick* prevents Humana from asserting indirect purchaser claims under the antitrust laws of Alaska, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Kentucky, Louisiana, Maryland, Massachusetts, Missouri, Montana, New Jersey, Oklahoma, Pennsylvania, South Carolina, Texas, Virginia, Washington, and Wyoming.[38] And as already discussed, Humana's antitrust and consumer protection claims fail under various state laws. Therefore, Humana's unjust enrichment claims should be dismissed there as

[38] *See United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1089-90 (N.D. Cal. 2014) (ruling that indirect purchasers "cannot circumvent the *Illinois Brick* prohibition absent authority from the courts of those states that would allow unjust enrichment claims to proceed" and dismissing unjust enrichment claims based on the laws of states that have not enacted *Illinois Brick* repealer statutes).

well.

3. Humana's Unjust Enrichment Claims Fail Under the Laws of States that Require Allegations of a Direct Benefit.

Under the laws of Alabama, Florida, Georgia, Idaho, Kentucky, Maine, Michigan, New Jersey, North Dakota, Pennsylvania, and Rhode Island, a plaintiff must confer a direct benefit on a defendant to recover for unjust enrichment.[39] Here, Humana—pursuing claims through its insurance arm, as an indirect purchaser—concedes it lacks privity of contract with Celgene and instead "indirectly purchased Thalomid and Revlimid" through "intermediar[ies] in the chain of distribution." Compl. ¶¶ 433-434. As an indirect purchaser, Humana's unjust enrichment claims under the above states' laws are clearly deficient.

4. Humana Fails to Allege Unjust Enrichment Under New York Law.

To state an unjust enrichment claim under New York law, "there must be some relationship between the parties, though it need not be as close as privity of contract." *In re Amaranth Nat. Gas Commodities Litig.*, 587 F. Supp. 2d 513, 532 (S.D.N.Y. 2008).

---

[39] *See Cole v. NIBCO, Inc.*, No. 3:13-cv-07871, 2015 WL 2414740, at *14 (D.N.J. May 20, 2015) (applying Alabama law); *Kopel v. Kopel*, 229 So. 3d 812, 818 (Fla. 2017); *Archer v. Holmes*, No. 1:17-CV-2051-TWT, 2018 WL 534475, at *5 & n.36 (N.D. Ga. Jan. 23, 2018); *Stevenson v. Windermere Real Estate/Capital Grp., Inc.*, 275 P.3d 839, 842 (Idaho 2012); *Pixler v. Huff*, No. 3:11-CV-00207-JHM, 2011 WL 5597327, at *11 (W.D. Ky. Nov. 17, 2011); *Rivers v. Amato*, No. CIV. A. CV-00-131, 2001 WL 1736498, at *4 (Me. Super. June 22, 2001); *A & M Supply Co. v. Microsoft Corp.*, No. 274164, 2008 WL 540883, at *2 (Mich. Ct. App. Feb. 28, 2008) (per curiam); *Block v. Jaguar Land Rover N. Am., LLC*, No. 15-5957 (SRC), 2016 WL 3032682, at *4 (D.N.J. May 26, 2016) (applying New Jersey law); *Midland Diesel Serv. & Engine Co. v. Sivertson*, 307 N.W.2d 555, 557 (N.D. 1981); *Stutzle v. Rhone-Poulenc S.A.*, No. 002768, 2003 WL 22250424, at *2 (Pa. Com. Pl. Sept. 26, 2003); *J.P. Morgan Chase Bank, N.A. v. Leigh*, No. 11-246ML, 2011 WL 4351584, at *2 (D.R.I. Aug. 23, 2011), *report and recommendation adopted*, No. 11-246 ML, 2011 WL 4351561 (D.R.I. Sept. 15, 2011).

Here, Humana's relationship with Celgene is "too attenuated," *Sperry v. Crompton Corp.*, 863 N.E.2d 1012, 1018 (N.Y. 2007), because Humana's insurance arm is connected to Celgene only through "intermediar[ies] in the supply chain" from which it purchases Thalomid and Revlimid, Compl. ¶¶ 433-34. This claim should be dismissed. *See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 216 (E.D. Pa. 2009) (applying New York law).

CONCLUSION

Humana's Complaint should be dismissed.

By: _____

Daniel R. Guadalupe
Norris McLaughlin, P.A.
400 Crossing Blvd., Eighth Floor
P.O. Box 5933
Bridgewater, N.J. 08807
Tel: (908) 722-0700
drguadalupe@norris-law.com

John E. Schmidtlein (*pro hac vice*)
Benjamin M. Greenblum (*pro hac vice*)
725 12th Street, NW
Washington, DC 20005
Tel: 202-434-5000
jschmidtlein@wc.com
bgreenblum@wc.com

Counsel for Celgene Corp.